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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,858	09/25/2001	Jean J. Frechet	18062G-003510US	1612
20350	7590	05/24/2004		EXAMINER
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				RILEY, JEZIA
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/963,858	FRECHET ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 May 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
  - 4a) Of the above claim(s) 1-7,11-14,20-22 and 24-48 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 8-10 and 15-19 is/are rejected.
- 7) Claim(s) 23 is/are objected to.
- 8) Claim(s) 1-48 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/18/02.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The proposal of the alternative Grouping Scheme (ASG) by applicants has been reviewed. The examiner agrees that the ASG proposed by applicants is appropriate and therefore the restriction requirement will be based on said ASG. Therefore the second restriction requirement made by the previous examiner is being withdrawn.
  
2. Applicant's election of Group II on 5/3/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Further applicants elected species A has being star poly(alkylene)oxide, R5 as H, and R6 as therapeutic agent. Claims 8-10, 15, 17-19, 23 read on said species. After searching said claimed elected, species with R6 being therapeutic agents, the examination of the instant application has been extended to include R6 being H, diagnostic agents, analytical agents, and moieties comprising a reactive group, since dendrimers comprising a subunit as claimed in claim 8 with R6 being a therapeutic agent seem free of prior arts. Therefore Claims 8-10, 15-19, and 23 have been examined and claims 1-7, 11-14, 20-22, 24-48 have been withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8-10, 15-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hult et al. (US5,418,301).

Hult discloses dendritic macromolecules see figure 1, where A is O, and a component of a polymer and R5 and R6 are H and a moiety comprising a reactive group.

Instant claims 15 and 16 are also rejected because said claims do not specifically state that R5 or R6 are specifically therapeutic agents. The embodiment of claim 8 is still included in those claims which include therefore R5 and R6 being H or a moiety comprising a reactive group.

6. Claims 8-10, 15-19 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Magnusson et al. (Macromolecules 2000, 33, 3099-3104).

Magnusson et al. disclose hyper branched polymers from 2,2-Bis(hydroxymethyl)propionic acid, dendrimer shown in page 3100. Said dendrimer is identical to said instant claim where R5 is H, A is O and a component of a polymer and said polymer is a star polyalkyleneoxide (see core of the dendrimer as shown in figure 1. And R6 is a H or a moiety comprising reactive group as shown on the end of one branch of the dendrimer (figure 1).

Instant claims 15 and 16 are also rejected because said claims do not specifically state that R5 or R6 are specifically therapeutic agents. The embodiment of claim 8 is still included in those claims which include therefore R5 and R6 being H, or a moiety comprising a reactive group.

7. Claims 8-10, 15-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trollsas et al. (*Macromolecules*, 198, 31, 3439-3445)

Trollsas et al. discloses dendrimer comprising a subunit identical to the instant claim 8, where A is O and a component of a polymer and said polymer is a polyalkyleneoxide, R5 is and R6 can be H or attached together to form a structure as in instant claim 8 comprising the aromatic ring. (see pages 3439-3440).

Instant claims 15 and 16 are also rejected because said claims do not specifically state that R5 or R6 are specifically therapeutic agents. The embodiment of claim 8 is still included in those claims which include therefore R5 and R6 being H

8. The claims have added functions which the prior art has not analyzed, such as the dendrimer is substantially free of urea side products; but given the 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare composition which appeared to be identical, the prior art therefore suggests the instant application under 35 U.S.C. § 103(a).

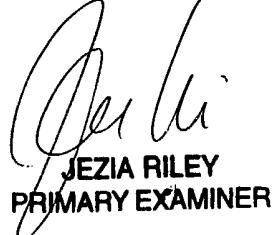
9. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/23/04



JEZIA RILEY  
PRIMARY EXAMINER